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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------|--------------------------------------|----------------------|---------------------|------------------|
| 10/695,668 | 10/28/2003 | Thomas W. Burns | GLAUKO.011CP2 | 4063 |
| | 7590 10/19/2007 RTENS OLSON & BEA | EXAMINER | | |
| 2040 MAIN ST | REET | DAWSON, GLENN K | | |
| FOURTEENTI IRVINE, CA 9 | | · | ART UNIT | PAPER NUMBER |
| | | | 3731 | |
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| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 10/19/2007 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com eOAPilot@kmob.com

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| | Applicant(s) | | $\overline{\cdot}$ |
| • | BURNS ET AL. | | |
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| U.S.C. § 119(a) | -(d) or (f). | | |
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| Interview Summary | (PTO-413) | | |

| • | Application No. | Applicant(s) | | | | |
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| , | 10/695,668 | BURNS ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Glenn K. Dawson | 3731 | | | | |
| The MAILING DATE of this communication Period for Reply | appears on the cover sheet with the o | correspondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR RE WHICHEVER IS LONGER, FROM THE MAILING - Extensions of time may be available under the provisions of 37 CFF after SIX (6) MONTHS from the mailing date of this communication If NO period for reply is specified above, the maximum statutory per - Failure to reply within the set or extended period for reply will, by state Any reply received by the Office later than three months after the material patent term adjustment. See 37 CFR 1.704(b). | DATE OF THIS COMMUNICATION 1.136(a). In no event, however, may a reply be tir- iod will apply and will expire SIX (6) MONTHS from atute, cause the application to become ABANDONE | N. nely filed the mailing date of this communication. ED (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on <u>0</u> | 1 August 2007. | | | | | |
| 2a)⊠ This action is FINAL . 2b)☐ T | his action is non-final. | | | | | |
| 3) Since this application is in condition for allo | 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| closed in accordance with the practice unde | er <i>Ex parte Quayle</i> , 1935 C.D. 11, 49 | 53 O.G. 213. | | | | |
| Disposition of Claims | | • | | | | |
| 4) ☐ Claim(s) 1-10 is/are pending in the applicate 4a) Of the above claim(s) is/are without 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-10 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and | drawn from consideration. | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Exam 10) The drawing(s) filed on is/are: a) a Applicant may not request that any objection to the Replacement drawing sheet(s) including the con 11) The oath or declaration is objected to by the | accepted or b) objected to by the the drawing(s) be held in abeyance. Serection is required if the drawing(s) is ob | e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d). | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal F 6) Other: | ate | | | | |

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lynch, et al.-6450984 in view of Paraschac, et al.-6050999 and Hill-6533768.

Lynch discloses the implant for being received in Schlemm's canal for treating glaucoma. It includes inflow and outflow portions as seen in fig. 3A, 3D, 4 with standoffs 32 for placement in the claimed locations. However, it is not specifically disclosed as being put in a sterile package with either one or two inserters, cartridges and a plurality of implants, or a plurality of inserters each with 1 implant. Paraschae discloses that it was known to place a plurality of ocular implants into a cartridge and placing it in a sterile package, or loading the filled cartridge into the inserter and then sterilizing the whole kit together. The cartridge has a plunger for pushing only the last implant out of the inserter at a time. Placing the system in a sterile package would have been obvious to ensure the device was sterile during shipping and before implantation. Hill discloses an inserter as shown in fig. 7. It would have been obvious to have loaded a plurality of Lynch's implants into one implanter, such as that disclosed by Hill, as this has been shown to be an effective device for implanting these implants into the proper position in the eye for treating glaucoma. As it might be necessary to put implants in both eyes of a single patient, providing a plurality of implants in the inserter would have facilitated the dual procedure. Additionally, to have provided a plurality of cartridges, each with a plurality of implants in them, along with a plurality of inserters in a single "kit" would have been obvious in the event that the physician desired to prevent possible infection between patients or even to prevent infection between two eyes of the same patient, and in order to provide a convenient package by which all of the instruments

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necessary to carry out a plurality of procedures could be stored in a single easy to obtain location. Providing them in a single sterilized package along with the cartridges and/or inserter each in their own sterilized package inside the larger "kit" package would have been obvious to keep the individual components sterile until their use is desired.

Response to Arguments

Applicant's arguments filed 08-01-2007 have been fully considered but they are not persuasive and are most in view of the newly applied reference to Paraschac, et al.

Paraschac discloses the placing of a plurality of implants into a cartridge and providing an inserter. The cartridge can be placed in the inserter and used to implant a plurality of ocular implants into a patient(s). The examiner contends that one skilled in the art would have found the placing of implants into a cartridge(s) and/or into an inserter or into a sterile kit package with all of these components would have been obvious. One would have had every expectation of success when making the claimed combination and the prior art devices would perform in substantially the same manner as previously disclosed following combining the teachings of the references.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K. Dawson whose telephone number is 571-272-4694. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Glenn K Dawson Primary Examiner Art Unit 3731

Gkd 09 October 2007